DETAILED ACTION

The amendment filed 20 June 2011 has been received, entered and carefully considered. The following information has been made of record in the instant amendment:

1. Claims 1-111, 125 and 139-141 have been canceled. Claims 1-111 were cancelled in the amendment filed 15 October 2010. Claims 125 and 139-141 have been cancelled in the instant filing.

2. New Claims 163-165 have been added.

3. Claims 112, 123-124, 128, 144 and 155-157 have been amended.

4. Remarks drawn to rejections under 35 USC 112, second paragraph, 102 and 103.

Claims 112-124, 126-138, 142-165 are pending in the case.

The following have been overcome:

5. The rejection of Claims 112-116, 118-122 and 161 under 35 U.S.C. 102(b) as being anticipated by Iaccheri et al (US 4,753,804) and,

The rejection of Claims 112, 115, 117, 126-127, 144-154 and 158-160 and 162 under 35 U.S.C. 102(b) as being anticipated by Brantman (US 4,687,782) and,

The rejection of Claims 112-116, 118, 120-126, 128-132, 134, 136-142 and 155-157 under 35 U.S.C. 102(b) as being anticipated by Pola (WO 01/95915) have all been overcome in view of applicants amendment. The cited art do not expressly teach the amounts of L-carnitine and the agent as recited in the amended claims.

The following are new ground(s) or modified rejections necessitated by Applicant's amendment, filed 20 June 2011, where the limitations in pending claims 112, 123-124, 128, 144 and 155-157 as amended now have been changed. Specifically, claim 112 has been amended to recite the limitations, "amount of L-carnitine or analogue thereof is 0.25g to 3g and the amount of the agent is 30g to 450g". In claims 123 and 128, the terms "2.5g and 450g" have been deleted and the limitation, "30g and 120g" has been added. ". In claim 124 the limitation, "2.5g" has been deleted and the limitation, "230g" has been added. In claim 144, the limitations, "L-carnitine or analogue thereof is provided in sufficient quantity to increase blood/plasma carnitine concentration and wherein the agent is provided in sufficient quantity to increase insulin activity in the tissue by increasing the amount of insulin in the blood/plasma" has been added. In claim 155 the limitation, "2.5 g and 450g" has been deleted and the limitation, "30g to 450g has been added. In claim 156, the limitation "2.5g to 285g" has been deleted and the limitation "30g and 120g' has been added. In claim 157, the limitation, "2.5g and 120g" has been deleted and the limitation "230g and 185g' has been added. Therefore, rejections from the previous Office Action, dated 21 january 2011, have been modified and are presented below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 112-162 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention is being maintained for reasons of record and is reiterated below.

Claim 112 recites the term analogue thereof. In the absence of the specific analogues recited via chemical structures or the chemical names, the identity of said analogs would be difficult to define and the metes and bounds of the said analogs applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in this and all other claims in which the said terms are recited. In the absence of a definition for the analogs in the claims or in the specification the said term is examined as drawn to any substance that has an L-carnitine moiety attached to it. The said terms are recited in claims 112, 128 and 144.

Claims 113-127, 129-143 and 145-162 which depend from base claims that are unclear/indefinite are also rendered unclear/indefinite.

Response to Applicants Arguments

Applicants have traversed the rejection under 35 USC 112, second paragraph above arguing that:

1. L-carnitine analogs were well known in the art at the time the instant application was filed. The references cited by applicants disclose examples of such analogues. Applicants also cite definition of the term analog given in Collins English Dictionary.

2. In addition Examiner has cited the teaching of Pola wherein substances like propionyl carnitine, acetyl carnitine are cited as analogs of carnitine. Thus the term analog would be given the meaning as including substances like propionyl carnitine and acetyl carnitine.

Applicants' arguments have been considered but are not found to be persuasive. At page 5 of the specification there is a reference to carnitine but no clear definition as what all are intended as analogs of carnitine in the instant invention is mentioned. The dictionary definition cited is a general definition with an example of an alcohol and a thiol. In the references cited two of them mention carnitine salts and the third one uses propionyl carnitine for studying its effects on ischemic heart. The citations do not clearly teach what are all considered as analogs of carnitine in the instant invention. Since there is no clear definition the Examiner has used the teachings of Pola of substance like propionyl carnitine as analogs. The rejection is being maintained.

The following rejection under 35 USC 112, second paragraph is made of record necessitated by applicants' amendment.

Claims 163-165 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New claims 163-165 recite, "wherein L-carnitine or an analog thereof is L-carnitine". It is not clear what applicants intend by the said recitation. An analog of L-carnitine cannot be L-carnitine itself, especially in light of the dictionary definition that applicants have cited.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 112-124, 126-138, 142-165 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pola (WO 01/95915; of record) in view of Brantman (US 4,687,782; of record) and Iaccheri et al (US 4,753,804; of record).

Pola teaches a composition comprising L-carnitine, propionyl carnitine, acetyl carnitine, and isovaleryl carnitine (considered analogs of carnitine in the absence of a definition for analog), each 250mg and ribose 2.5g (the agent to increase insulin concentration). It can be seen that the ratio of ribose to each of L-carnitine and the analogs is 10:1 (page 7, composition #

7).The compositions can be made as syrup (page 10, line 2; same as solution). Pola teaches the use of 0.25g of L-carnitine which is the lower end of the range recited for L-carnitine in the instant claims.

Brantman teaches a composition (Example 1, cols 5-6) in which L-carnitine is 0.025g, soy protein is 2.5g (the agent). The ratio of agent to L-carnitine is at least ten to one. This reads on part of the limitation of claim 115). The same composition also has the amino acids isoleucine, leucine and valine. The amount of these amino acids is at least ten times that of L-carnitine (part of the limitations of claim 115 and limitation of claim 117 and new claims 163-165).

The above composition of Brantman has sucrose as one of the ingredients (25g). This is the agent to increase insulin concentration. The composition is made up as a unit in 400 ml of water (col. 5, lines 55-57). Sucrose is present at a concentration of 25g/400ml water, which is 60mg/ml. These teachings read on the limitations of claims 126-127, 144-151 and 158-159. The amount of sucrose is at least ten times that of L-carnitine (limitations of claims 152-154). The amounts of amino acids (which are also agents that increase insulin concentration) are 34 times that of L-carnitine (reads on limitations of claims 152-154).

Brantman's composition is for facilitating the adaptation of skeletal muscles in humans. Muscles require carnitine (abstract; col. 1, lines 33-38; col. 1, lines 54-60; col. 2, lines 61-63; Example 1 at cols. 5-6). The composition is for oral administration (col. 4, lines 62). This teaching is seen to read on claims 160 and 162.

Brantman teaches that in the composition of his invention L-carnitine can be used in the range of 0.3 to 2.0g (col. 4, lines 45-47). The ranges of amino acid proportions may be varied to

refine to adaptive responsiveness (col. 5, lines 3-9). One of ordinary skill in the art will recognize from this teaching that the composition can be made with different amounts of L-carnitine as needed including the amounts instantly claimed and the amount of the agent can be adjusted to be at least ten times or more compared to that of carnitine, since a composition comprising such a ratio is taught.

Iaccheri et al teaches a composition comprising L-carnitine (500 parts by weight), glucose and fructose (both 5000 parts by weight; both are agents that increase insulin concentration; col. 10, Example 6). The ratio of L-carnitine to glucose or fructose is 10:1 (limitations of claims 112, 120-122). The glucose and fructose (both are carbohydrates: agents as instantly recited) present in the composition read on the limitations of claims 113-116, 118-119. The composition of Iaccheri is prepared in the form of a pellet. This reads on the limitation of claim 161. Specifically he teaches the use of glucose and fructose (agents recited in instant claim 135) in his composition which is similar to the composition of Brantman.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition as instantly claimed since analogous compositions comprising the components of the instant composition in the proportions claimed are taught in the prior art. The proportions can also be varied according to individual needs according to the prior art.

One of ordinary skill in the art would be motivated to make the claimed compositions containing the claimed proportions since the components including L-carnitine and the other amino acids maximize protein synthesis in skeletal muscles (Brantman, col. 4, lines 22-30). . One of ordinary skill in the art would adjust the amounts of the active agents in the composition

in order to get a composition that would provide the optimal beneficial effects. Such is routine and also well within the skill level of the artisan.

MPEP 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusatory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ,82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

According to the rationale discussed in KSR above, the rationale in (A) and (F) above are seen to be applicable here since based on the prior art teachings, L-carnitine, other amino acids and the components as instantly claimed are known to improve protein synthesis in skeletal muscles and provide diet supplements to promote muscle adaptation. Thus, it is obvious to combine prior art elements and improve the product of the prior art to yield predictable results.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Response to Applicants Arguments

Applicants have traversed the rejection under 35 USC 103(a) of record arguing that they have surprisingly found that the administration of carnitine with an agent that increases insulin concentration to a subject results in substantially increased carnitine retention in the tissues of the subject. The beneficial properties are unexpected.

Applicants' arguments are not found to be persuasive. The prior art of record teaches compositions comprising the active agents present in the instantly claimed composition. It also teaches that L-carnitine, other amino acids and the components as instantly claimed are known to improve protein synthesis in skeletal muscles and provide diet supplements to promote muscle adaptation. The results that applicants claim as unexpected is taught in the prior art and hence the combination of the prior art renders the instant invention obvious.

Conclusion

Claims 112-124, 126-138, 142-165 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 9.00am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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